IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IAN WALLACE, Plaintiff, vs. PHARMA MEDICA RESEARCH, INC.; TRIS PHARMA, INC.; ROXANE LABORATORIES, INC.; HIKMA LABS, INC.; and WEST-WARD COLUMBUS, INC., Defendants.	)	Cause No. 4:18-cv-01859-PLC

DEFENDANT TRIS PHARMA, INC.'S STATEMENT OF UNDISPUTED FACTS

COMES NOW Defendant, Tris Pharma, Inc. ("Tris"), by and through their undersigned counsel, and for their Statement of Undisputed Facts to be included in their Motion for Summary Judgment in accordance with Federal Rule of Civil Procedure 56 and Local Rule 4.01 states to the Court as follows:

1. On December 9, 2019 Plaintiff, Ian Wallace, filed his Second Amended Complaint against Hikma Labs, Inc., Pharma Medica Research, Inc. ("Pharma"), Tris and others for injuries he allegedly sustained in contracting Hepatitis C during a blood drawing process at Pharma's St. Charles facility while participating in a medical study. See Second Amended Compliant, attached hereto as Exhibit A.

2. There were two medical studies which were designed to test a new medications. One of the medical studies was to test new medication designed, manufactured, supplied and created by Tris. See Exhibit A ¶ 12.

3. Defendant Pharma operated a screening clinic and Phase 1 clinic in St. Charles, Missouri. See Exhibit A ¶ 2.

4. Pharma conducted studies of medications designed by others and included tests on human volunteers. See Exhibit A ¶ 12.

5. These tests included health studies including blood draws. See Exhibit A ¶ 12.

6. Defendant Tris contracted with Pharma to conduct a study of a certain medication provided by Tris. See Exhibit A

7. Plaintiff was a voluntary participant in the study. See Exhibit A ¶ 3.

8. Tris contracted with Pharma, where Pharma and Tris specifically agreed that Pharma was not an agent of Tris.

11. Independent Contractor Status

11.1 It is understood and agreed that CRO is an independent contractor and will not have any right to any of Tris benefits, not for any purposes be deemed or intended to be an employee of Tris. CRO agrees to make any payments or withdrawing required by the Internal Revenue Code of 1986, as amended, the regulations promulgated thereunder, social security and any related statutes or regulations.

11.2 It is further understood that CRO is not an agent of Tris and Tris is not an agent of CRO and neither party is authorized to bind the other party with respect to any third party.

See Master Service Agreement attached hereto as Exhibit B.

9. At all times relevant, Shabaz Kahn, M.D., was the vice president of clinical operations at Pharma. See Deposition of Shabaz Khan, M.D., attached hereto as Exhibit C.

10. Pharma was a contract research organization that did clinical trials for pharmaceutical companies. See Exhibit C, P. 6, L. 5-7.

11. Pharma's clinical location in St. Charles dealt with all clinical activities where Volunteer participants came and participated in a study. See Exhibit C, P. 14, L. 23-24; P. 15, L. 12-17.

12. Part of what Pharma did was take a brand name medication and conduct testing on the generic equivalent. See Exhibit C, P. 20, L. 5-9.

13. Pharma worked on a contract basis with pharmaceutical companies to test and gather data for testing pharmaceuticals that the pharmaceutical companies wanted to market. See Exhibit C, P. 19, L. 12-17.

14. Pharma conducted its studies pursuant to a protocol. See Exhibit C, P. 53, L. 6-8.

15. A scientific affair team and protocol writing team created the protocol for each study. See Exhibit C, P. 56, L. 5-9.

16. The sponsor did not have input in creating the guidelines for a study. See Exhibit C, P. 57, L. 3-6.

17. The guidelines required to be included in the protocol were determined by the FDA. See Exhibit C, P. 57, L. 6-7.

18. Pharma had a team of protocol writers who drafted protocols for each study. See Exhibit C, P. 61, L. 8-9.

19. The protocol writers were Pharma employees. See Exhibit C, P. 61, L. 19-20.

20. Pharma was required to draw blood from a needle stick rather than a catheter as the FDA did not approve a device that was used on a catheter called a mandarin or an obturator. Exhibit C, P. 81, L. 12-18.

21. The protocol governed how a particular study will be conducted. See Exhibit C, P. 102, L. 1-4.

22. Each study's protocol was prepared by a Pharma writing team which dictated a study's specific conduct. See Exhibit C, P. 103, L. 17-18.

23. Heather Jordan, M.D., worked as a principal investigator for Pharma from March 2015 until May 2019. See Exhibit D, Deposition of Heather Jordan, M.D., P. 12, L. 10-15; P 17, L. 20-21.

24. Dr. Jordan's duties included making sure each study to which she was assigned was conducted according to the protocol. See Exhibit D, P. 21, L. 19-21.

25. Protocol (or study guidelines) governed everything ranging from what medication to administer to the time a participant's blood was to be drawn and tested. See Exhibit D, P. 22, L. 9-13.

26. Protocol (or study guidelines) determined how the blood was to be drawn. See Exhibit D, P. 22, L. 14-17.

27. Protocol (or study guidelines) governed how the entire study was to be conducted. See Exhibit D, P. 23, L. 5-9.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was electronically filed and served to counsel via the Court's e-filing system on this 12th day of October, 2020, addressed to the following attorney(s) of record:

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